IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 10/565,331

Confirmation No. 2246

Applicant: DeFrees et al.

Filed: September 11, 2006

TC/AU: 1644

Examiner: Phuong N. Huynh

Docket No.: 705704 (Client Reference No. NEO000266.1US/371; 7992.204-US)

Customer No.: 23460

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132 OF SHAWN DeFREES

Sir:

I, Shawn DeFrees, hereby declare the following:

1. I am Chief Scientific Officer at Seneb BioSciences, Inc. I am named as an inventor of the above-referenced patent application. I am also a part-time consultant to BioGeneriX, which is the licensee of the above-referenced patent application.

2. My curriculum vitae is attached hereto and provides the details of my educational and employment experience.

3. I understand that the claims of the above-referenced patent application are directed to compounds comprising an antibody joined to a toxin by way of an intact glycosyl linking group and a bond or spacer moiety. In order to prepare and use such compounds based on the information in the patent application, it is not necessary to know the binding specificity of the antibody for any target. Well prior to 2006, a variety of antibodies were being used for therapeutic purposes. The compounds

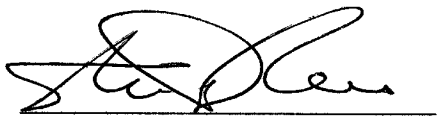
claimed in the above-referenced patent application, incorporating those antibodies, can be used in the same manner as such antibodies.

4. I have reviewed the following portions of U.S. Patent 7,125,843, on which I am listed as a co-inventor: Table 2; Figure 49A-51C; Col. 12, lines 33-35; Col. 36, line 65; Col. 45, line 60 through Col. 47, lines 1-3; Col. 67, lines 18 and 34-67; Col 68, line 3; Col. 84, lines 46-67; Col. 143, lines 34-41; Col. 141, lines 30-42; Col. 166; Col. 339, lines 1-13; and Col. 145, line 66 through Col. 146, line 5.

5. These portions of the '843 patent describe subject matter invented by me or derived from my work.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further than these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Feb. 17, 2010
Date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CURRICULUM VITAE

EXECUTIVE SUMMARY

Experienced manager with extensive experience at managing all aspects of research and development for both biologics and small molecule therapeutics. Committed visionary, creative leader and innovative problem solver with the ability to communicate at all levels in the organization and a proven track record at identifying and developing new products and product opportunities.

PROFESSIONAL EXPERIENCE

Consulting Services | North Wales, PA
Pharmaceutical and Biologics Industry Consultant
2009-present

Provide scientific services for research and product development companies that include BiogeneriX AG and Virdante Pharmaceuticals, Inc.

Neose Technologies, Inc. | Horsham, PA
Sr. Vice President, Research and Development
Vice President, Research and Development
Senior Director, Research
Senior Director, New Product Development
1999-2009

Directed research and development that included the Departments of Protein Chemistry, Molecular Biology, Biochemistry, Fermentation, Pharmacology, Analytical Chemistry, Medicinal Chemistry and Process Development. Advanced techniques in protein chemistry, chemistry, drug discovery, lead optimization, protein design, protein expression, assay design and implementation, process development and cGMP manufacture of therapeutics (protein and small molecule) were utilized. Managed up to 35 employees through project and department functions.

Key Accomplishments:

- Created two therapeutic platforms, Glycoconjugation (biologics) and Glycolipids (small molecules), that produced all of the current therapeutic proteins and small molecule products in preclinical and clinical development (two products in Phase I, two products in Phase II and one in Phase III).
- Created share holder and corporate value that exceeded $200 MM in funding, two corporate partnerships (Novo Nordisk and BiogeneriX) and the sale of Neose Technologies, Inc. assets to our partners.
- Developed numerous cGMP upstream and downstream production processes (fermentation through formulation) for numerous proteins and glycoproteins (for example, EPO, G-CSF, Factors VII, VIII and IX, growth hormone, BMP-7, antibodies, ST3Gal1, core-1-GalT1, GalNAcT2, ST3Gal3, production enzymes; most with and without PEGylation).
- Developed new cell lines and novel expression systems (bacteria, insect cells and CHO) for the production of proteins, glycoproteins, oligosaccharides and glycolipids including a new bacterial expression system that produces glycoproteins, directly.

- Developed several cGMP manufacturing process for small molecule drug substances and intermediates including the development and implementation of a production process for a Phase III study of a BMS cancer vaccine.
- Identified numerous new development candidates (e.g. ID1071, ID1005, P153, P195) using protein engineering (rational design, molecular modeling and directed evolution), medicinal chemistry (rational design, computer modeling, lead optimization, parallel synthesis) and drug discovery screening for both biologics and small molecule therapeutics.
- Experienced with disease states in such areas as inflammation, oncology, neurology, cardiovascular, immunology, and hematology.
- Always met or exceeded all project timelines that were on budget for internal projects, partnerships, academic collaborators and CMO's (USA, Canada and EU).
- Prolific inventor and problem solver with over 400 patent and patent applications worldwide including therapeutic compositions (proteins and small molecules) and production technologies. Of these, 57 are granted worldwide, 126 are pending in the US, and 30 are granted in the US.
- Managed the strategic implementation and direction of Neoses's patent portfolio.

Cytel Corporation | San Diego, CA
Director, Medicinal Chemistry
Group Leader, Medicinal Chemistry
Senior Staff Scientist, Chemistry
Staff Scientist, Chemistry
1991-1999

Directed product discovery and development activities for the chemistry group related to both therapeutic and commercial products. Departmental responsibilities and activities included lead identification, optimization, drug design and early development of new manufacturing processes in the disease areas of inflammation, graft rejection and cancer. Managed 7 chemists.

Key Accomplishments:

- Created sialyl Lewis X carbohydrate and small molecule non-carbohydrate analogs as inhibitors of selectin adhesion and inflammation with improved potency and pharmacodynamics.
- Identified a new class of dermal anti-irritant products and enabled a manufacturing process for use by Estee Lauder.
- Developed an improved enzymatic manufacturing process for producing complex oligosaccharide products for Xenotransplantation and Infant Formula for Nextran/Baxter Pharmaceuticals and Ross Laboratories.
- Created a new vaccine construct that elicited a potent and selective IgG immune response to oligosaccharides and polysaccharides used by Epimmune, a spin-off of Cytel Corporation.
- Discovered multiple new product opportunities based on glycoprotein and small molecule therapeutics for treating peptic ulcers, pseudomembranous colitis and psoriasis.
- Created a novel therapeutic platform and small molecule non-carbohydrate structures as inhibitors of glycosyltransferases (e.g. FTVII, ST6Gal1 and GalT1) used to start a new biotechnology company, Abaron Biosciences.

Cytel Corporation | San Diego, CA
Team Leader, Corporate Operations Committee (COC)
Team Member, Corporate Operations Committee (COC)
1997-1999

Corporate Operations Committee reported directly to the COO/CMO. Directed corporate operational issues that included corporate policies and practice regarding the performance management system, equity assessment, benefits, and safety. Operated the performance management system which included

monitoring team performance, resource allocation, and departmental and team budgets. The team managed up to 65 employees.

Key Accomplishments:

- Created and established a new performance management system as part of the COC based on a matrix management system that emphasized compensation based on team and employee performance.

Cytel Corporation | San Diego, CA
Program Leader, Glytec Business Unit
Project Leader, Glycosyltransferase Inhibitor Project
Project Leader, New Products and Technology
Project Leader, Selectin Inhibitor Project
1994-1999

Supervised multiple teams in both Manufacturing and Research to leverage experience and technologies in the fields of bioactive carbohydrates and small molecule non-carbohydrate mimetics. Managed up to 26 employees.

Key Accomplishments:

- Delivered products and projects on time and under budget as outlined in the strategic and operational plans.
- Managed the last 3 yrs of a 5 yr $70 million dollar alliance with Sumitomo Pharmaceuticals to identify and develop selectin adhesion inhibitors as a treatment for inflammatory disease.
- Directed project teams in the Glytec Business Unit and managed relationships with Nextran/Baxter Pharmaceuticals, Ross Laboratories and Estee Lauder to develop product opportuntities in Xenograph Rejection, Infant Formula Additives, and anti-reddening agents, respectively.
- Successful project completions resulted in significant project milestone payments.

Schering-Plough Corporation | Belleville, NJ
Associate Principal Scientist, Medicinal Chemistry Department
Senior Scientist, Medicinal Chemistry Department
1988-1991

Medicinal chemist in the cardiovascular group focused on the synthesis of novel cGMP phosphodiesterase inhibitors, endothelin processing enzyme inhibitors, and ANF potentiation inhibitors. Managed several direct reports.

Key Accomplishments:

- Designed and synthesized a series of novel heterocyclic and nucleoside analogs of cGMP as cPDE inhibitors. One structure became the lead compound in an anti-cancer project.
- Developed, synthesized and patented a series of novel transition state inhibitors and peptidomimetic structures targeting the endothelin processing protease.
- Used computer modeling (Sybyl and Macromodel programs) to design drugs with improved potency and create novel scaffolds.

EDUCATION/PROFESSIONAL DEVELOPMENT

Postdoctoral Research Associate, Total synthesis of Brevitoxin B, University of Pennsylvania. Professor K.C. Nicolaou.

Ph.D., Synthetic Medicinal Chemistry, Purdue University. Professor John Cassady.
Thesis - "I. Synthesis and Kinetics of Dihydroorotate Dehydrogenase Inhibitors and Their Antineoplastic

Effects. II. Myristic Acid Analogs as Tyrosine Protein Kinase and Tumor Inhibitors". Cumulative GPA = 5.94/6.00

B.S., Biochemistry (Chemistry Minor), Graduated Magna Cum Laude, Albright College.

Executive Development Program (Hagberg Consulting), Situational Leadership II (Ken Blanchard's Training and Development), Building High Performance Teams, Managing Change and Transition, Managing Meetings.

AWARDS

- Directors Award. Award given by the Board of Directors for exceptional contributions to the science and business at Neose Technologies (2002).
- Star Award acknowledging individual contributions to Cytel, (1996).
- Cytel's President's Award for outstanding contributions and an entrepreneurial spirit (1995).
- Cy-Fi Award, Cytel Corporation, for significant research contributions (1995).
- Cy-Fi Award, Cytel Corporation, for significant research contributions (1993).
- Cy-Fi Award, Cytel Corporation, for significant research contributions (1992).
- David Ross Fellowship, Purdue University (1984 and 1985).
- Bernville Laboratories Award for Excellence in Biochemistry, Albright College (1980).

PATENTS

Greater than 44 separate patent families represented by over 400 patents and patent applications worldwide, 57 granted worldwide, 126 pending and 30 issued patents in the US.

PUBLICATIONS/MEETING ABSTRACTS

Currently, 39 publications. List available upon request.

REFERENCES

Available upon request.